Research Article

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A CLINICAL STUDY ON PRAVAHIKA WITH SPECIAL REFERENCE TO AMOEBIC DYSENTERY AND ITS MANAGEMENT BY INDIGENOUS DRUGS

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ABSTRACT

Pravahika is a clinical condition where fecal matter expelled out with more Pravahana or Kunthana. Vata and Kaphaprakopaka ahara vihara are the mainetiological factors of this disease. The vitiated Vayu bring downwards the accumulated Kapha and expels it along with Mala very frequently with Pravahana. The main symptoms of this disease are Sapravahana Mala Pravriti (tenesmus), Muhurmuhur Malaktam (frequent defecation), Udara Shoola (pain abdomen) etc. It can be compared with Amoebic dysentery which is the second leading parasitic disease-causing death in humans after malaria. By considering the above problem an indigenous drugs compound was selected for clinical trial which contains Bilwa (*Aegle marmelos*), Sunthi (*Zingiber officinale*) and Pippali (*Piper longum*) in equal quantity to trim down the pathogenesis of the disease. A total no of 40 patients divided equally into two groups Group A and B were selected for this study. Simple random sampling method was used for the selection of the patients. The trial drug indigenous drugs compound was given to Group A patients and Group B patients were given with control drug Metronidazole. Group A patients have shownmild to moderate improvement whereas Group B patients shown better result to reduce sign and symptoms of this disease.

Keywords: Pravahika, Pravahana, Kunthana, Amoebic dysentery, Indigenous drugs.

INTRODUCTION

In the 21st century era of competition life people is changing their diet pattern, lifestyle and behavioral pattern, working with stress and strain which hampers the digestion and is causing so many GI disorders. Pravahika is one of them. It is one of the commonest diseases of Annavaha and Pureeshavaha srotas. Improper dietary habits and stressful lifestyle are the root causes for Agni Dushti and subsequently the disease Pravahika. Vata Dosha and Kaphadosha are mainly vitiated in this disease. The vitiated Vayu bring downwards the accumulated Kapha and expels it along with Mala very frequently with Pravahana[1]. Pravahika is described in Ayurvedic texts by various Acharyas. It is specially described in Sushruta Samhita[1], Ashtanga Hridaya[2] and Siddhanta Nidan[3]. It is included in Kaphaja Atisara by Acharya Charaka[4]. Sapravahana Mala Pravriti (tenesmus), Muhurmuhur Malaktam (frequent defecation), Udara Shoola (pain abdomen) etc. are the main symptoms observed in Pravahika[1]. It can be compared with Amoebic dysentery which is caused by the infection of intestinal protozoan *Entamoeba histolytica* and is the second leading parasitic disease-causing death in humans after malaria. Globally, it is responsible for 40,000 to 110,000 deaths in a year. It is distributed worldwide and poses a serious health threat in tropical and subtropical countries. In recent years the numbers of sufferers are becoming more, and the several formulations have been tried on various aspects of Pravahika, still we are not having a definite cure for the disease. Considering the above fact, a comprehensive approach is required to solve this problem. Some indigenous drugs compound was selected as clinical trial for this study which is described in Charaka Samhita of Atisara Chikitsa[5]. This formulation contains Bilwa (*Aegle marmelos*), Sunthi (*Zingiber officinale*) and Pippali (*Piper longum*) in equal quantity which possesses Ama Pachana, Agni Deepana and Grahi properties. Most of the ingredients of this formulation are having digestive, anti-amoebic, anti-diarrheal, anthelmintic, anti-haemorrhagic, anti-spasmodic, carminative, appetizer, anti-inflammatory, anti-bacterial and anti-ulcerative properties. So, considering above fact an attempt has been made to evaluate the efficacy of indigenous drugs in the management of Pravahika.

MATERIAL AND METHODS

Aims and objective

To evaluate the efficacy of indigenous drugs in the management of Pravahika and to compare the efficacy of indigenous drugs with a standard drug Metronidazole

Selection of Patients

For the present study, patients having symptoms of Pravahika were selected randomly from the OPD and IPD of the Gopabandhu Ayurveda Mahavidyalaya, Puri, Odisha, India. Study was carried out as per International conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP) or as per Declaration of Helsinki guidelines.

Inclusion Criteria

16-60 years of age group of both sexes were selected. The patients having classical symptomatology of Pravahika viz. Sapravahana Malapravriti, Muhurmuhurmalaktam, Udara Shoola, presence of trophozoites of *Entamoeba histolytica* and mucous in stool examination were selected for the study.

Exclusion Criteria

Ages below 16 years and above 60 years were not selected for the study. Patient suffering from acute diarrhoea, intestinal tuberculosis, ulcerative colitis, gastric and peptic ulcer, Diabetes mellitus, hypertension, IBS, Perforation, colonic cancer, prolapsed rectum and blood in stool were not selected for this study.

Investigations

Stool: Routine and microscopic examinations were carried out in this study.

Plan of study

Sampling: Simple random sampling method.

Group A: 20 patients were selected in this group and an indigenous drug was given internally at a dose of 5 g twice daily with Tila and Guda as Anupana after food.

Group B: 20 patients were treated with control drug Metronidazole at a dose of 400 mg thrice daily after food.

Assessment criteria

Scoring Pattern
Grading of parameters taken for assessment

Duration: 30 days, the assessments were carried out in each 15 days of the treatment.

Dietary Restrictions

The patients were strictly advised to follow the restrictions regarding food, food habits and lifestyle. They were instructed to avoid the possible causative factors of disease and causes for Agnimandya.

Study design

Single group design

Effectiveness of trial drug indigenous drugs compound and control drug metronidazole was assessed individually before and after treatment.

Double Group Design

Effectiveness of indigenous drugs compound with respect to control drug was assessed.

Subjective parameter

1. Sapravahana Malapravriti (Tenesmus)	
Grade 0	Nil.
Grade 1	Mild and occasional
Grade 2	Moderate and frequent
Grade 3	Severe and continuous
2. Muhurmuhur Malaktam (Frequent defecation)	
Grade 0	1-2 times per day
Grade 1	2-3 times per day
Grade 2	3-4 times per day
Grade 3	More than4 times
3. Udara Shoola (Pain in abdomen)	
Grade 0	Normal
Grade 1	Occasional/relieved after defection
Grade 2	Mild/ decreased after defection
Grade 3	Moderate/ not relieved after defection

Objective parameter

1. Presence of mucous in stool	
Grade 0	Nil
Grade 1	Occasionally (+)
Grade 2	Moderate amount (++)
Grade 3	Large amount (+++ or more)
2. Trophozoite of *E. Histolytica* in Stool	
Grade 0	Nil
Grade 1	Occasionally (+)
Grade 2	Moderate amount (++)
Grade 3	Large amount (+++ or more)

Here G0, G1, G2 and G3 denote Grade-0, Grade-1, Grade-2 and Grade-3 respectively

Assessment of Result

The assessment of progress was first noted at the end of 15 days and then 30 days. The above assessment scale was framed to assess the rate of improvement. All cases of both groups were followed up on the basis of criteria laid down in the progress report.

After 30 days of treatment, the result has been assessed as per the following heading:

1. Clinical assessment of result
2. Statistical assessment of result

Clinical assessment of result

- Complete Remission (Cured) – 100 % improvement in the symptoms.
- Markedly Improvement - 75 % or more relief in the symptoms (75%-99%)
- Moderate Improvement - 50 % or more relief in the symptoms (50%-74%)
- Mild improvement - 25 % or more relief in the symptoms (25%-49%)
- Unchanged- Less than 25 % improvement in the symptoms of Pravahika. (< 25%)

Statistical assessment of result

- Mean ± SD value of each sign and symptom before treatment and after treatment has been compared. To evaluate the efficacy of drug to different sign and symptom paired t-test is used for the purpose of test of significance.
- Unpaired t-test has been applied to observe the efficacy of trial drug in comparison to control drug for the different sign and symptom and the result was assessed through p-value.
- For the purpose of statistical assessment of result Mean ± SD of each sign and symptom before treatment has been compared with Mean ± SD value after treatment. Paired t-test is being used for the purpose of test of significance to evaluate the efficacy of drug to different sign and symptom.

Observation

Age group

Maximum numbers of patients i.e. 40% were from 27-37 years of age group followed by 32.5% patients were in the age group of 38-48 years, 15% were in the age group of 16-26 years and 12.5% of patients belonged to age group of 49-60 years.

Sex

Female patients were affected more (55%) as compared to male (45%).

Socio economic status

Most of the patients i.e. 50% belonged to lower middle class family, next to that 40% belonged to middle class family, 7.5% patients belonged to upper middle class and only 2.5% patients belonged to poor class family.

Diet

Majority patients 62.5% were taking mixed diet where as 37.5% patients taking vegetarian diet.

Dietary Habit

Maximum 67.5% patients were having dietary habit of Vishamasana while 12.5% Adhyasana, 12.5% were Anasana and 7.5% patients were having habit of Shamasanas.

Kostha

Majority of patients (57.5%) were of Madhya Kostha, 30% patients were of Mridu Kostha and 12.5% were of Krura Kostha.

Shareera Prakriti

35% patients were having Vata-Kaphaja Prakriti, 35% were of Pitta-Kaphaja and 30% patients were of Vata-Pittaja Prakriti.

Dosha involvement

Vatakapha dosha involvement patients were 52.5%, Pitta kapha dosha patients were 25% and Vatapitta dosha patients were 22.5%.

Agni

Maximum 55% patients had history of Mandagni, 32.75% patients had Vishamaagni, 7.5% patients had Teekshnagni and 05% patients had Samagni.

Bowel habit

45% patients were suffering from loose motion, 45% patients were having irregular bowel habit and only 10% patients were having constipation.

RESULT

After completion of treatment in trial group it was found that, 16 patients (80%) had got maximum improvement whereas rest 4 patients (20%) improved moderately and not a single patient got complete remission. Similarly in control group, 4 patients (20%) got complete remission, 16 (80%) patients got maximum improvement and not a single patient got moderately improvement and mild improvement. Statistical analyses showing the effectiveness of trial drug and control drug to different signs and symptoms are shown in the Table 1. Statistical analyses showing the effectiveness of Trial Drug in comparison to control drug with reference to different signs and symptoms are shown in the Table 2.

As regards to average percentage improved in different signs and symptoms, it has been found that after completion of treatment in trial group, most of the cardinal signs and symptoms like Sapravahana Malapravriti, Muhurmuhurmalaktam, Udara Soola and presence of mucous in stool were improved more than 86%. But in case of presence of *E. histolytica* in stool, improvement was 50% whereas in control group all the cardinal symptoms including presence of *E. histolytica* in stool also improved more than 88%.

DISCUSSION

Pravahika is a clinical condition where patient passes large amount of Kapha and Mala very frequently with Pravahana (Tenesmus)[1]. Agnidusti is the main etiological factors of this disease. So to counter the pathogenesis of this disease an indigenous drugs was selected as trial drug and control group patients were given with Metronidazole for the present study.

The trial drug contains three drugs viz. Bilwa, Sunthi and Pippali in equal quantity which is described in Charaka Chikitsa 19/114. This formulation was made in a Churna form. Tila and Guda were taken as Anupana[5]. Charaka has mentioned that Bilwa is considered as best Samgrahika, Deepaneeya and Vata-Kapha Prasamana in the context of agrya dravya[6]. The unripe fruit pulp of *A. marmelos* contains marmelosin which has been reported to have anthelmintic and anti-bacterial activity. Recently, several *in vitro* and *in vivo* studied have been conducted to confirm the anti-diarrhoeal property of *A. marmelos* due to tannic acid present in fruits. As the unripe fruit pulp affected the bacteria colonisation

to gut epithelium and production and action of certain enterotoxins. This suggests the varied possible mode of action of *A. marmelos* in Amoebic dysentery and infection form of diarrhoea[7]. Phytochemical studies shows that dry ginger rhizome contain gingerol and shogaol which have anti ulcerative effect by suppressing the gastric concentration and increasing mucin secretion. Again Shogoal have anti-inflammatory effect by inhibition of pro-inflammatory cytokines (IL-12, TNF- α, IL-1β, IL-8)[8]. Studies have revealed that a methanol extract of *Z. officinale* rhizomes possesses significant antibacterial activity against *E. coli*. Zingerone also showed protective effect in hyper motility diarrhoea that was linked to inhibition of gastrointestinal activity. Piperine isolated from the drug *P. longum* which possesses anti colic and analeptic potentialities[9]. The seeds of *Sesamum indicum* contains oleic acid and linoleic acid which increased the wound healing tissue mass. The total protein and DNA contents of the wound were increased by treatment with linoleic acid[10].

Table 1

S. N.	Sign and Symptom	Group		Mean + SD	Mean Diff + SD	D.F.	t-value	p-value	Remark
1	Sapravahan Mala pravriti	TG	BT	2.55 ± 0.60					
			AT1	1.45 ± 0.69	1.10 ± 0.45	19	11	<0.001	***
			AT2	0.30 ± 0.47	2.25 ± 0.64	19	15.76	<0.001	***
		CG	BT	2.20 ± 0.70					
			AT1	1.20 ± 0.52	1.00 ± 0.46	19	9.75	<0.001	***
			AT2	0.30 ± 0.47	1.90 ± 0.64	19	13.26	<0.001	***
2	Muhur Muhurmalaktam	TG	BT	2.50 ± 0.63					
			AT1	1.50 ± 0.52	1.00 ± 0.37	15	10.95	<0.001	***
			AT2	0.38 ± 0.50	2.13 ± 0.62	15	13.73	<0.001	***
		CG	BT	2.47 ± 0.52					
			AT1	1.47 ± 0.52	1.00 ± 0.38	14	10.25	<0.001	***
			AT2	0.20 ± 0.41	2.27 ± 0.59	14	14.79	<0.001	***
3	Udara Shoola	TG	BT	2.42 ± 0.69					
			AT1	1.37 ± 0.60	1.05 ± 0.52	18	8.75	<0.001	***
			AT2	0.32 ± 0.48	2.11 ± 0.66	18	13.95	<0.001	***
		CG	BT	2.21 ± 0.79					
			AT1	1.05 ± 0.78	1.16 ± 0.60	18	8.38	<0.001	***
			AT2	0.16 ± 0.37	2.05 ± 0.71	18	12.69	<0.001	***
4	Presence of *E. histolytica* in stool	TG	BT	2.40 ± 0.50					
			AT1	1.90 ± 0.72	0.50 ± 0.51	19	4.36	<0.001	***
			AT2	1.20 ± 0.70	1.15 ± 0.37	19	14.04	<0.001	***
		CG	BT	2.15 ± 0.75					
			AT1	1.05 ± 0.76	1.10 ± 0.45	19	11	<0.001	***
			AT2	0.15 ± 0.37	2.00 ± 0.65	19	13.78	<0.001	***
5	Presence of mucous in stool	TG	BT	2.00 ± 0.79					
			AT1	0.85 ± 0.67	1.15 ± 0.49	19	10.51	<0.001	***
			AT2	0.30 ± 0.47	1.70 ± 0.66	19	11.57	<0.001	***
		CG	BT	2.30 ± 0.66					
			AT1	1.05 ± 0.76	1.25 ± 0.44	19	12.58	<0.001	***
			AT2	0.20 ± 0.41	2.10 ± 0.72	19	13.08	<0.001	***

Table 2

S.N.	Sign and Symptom	Group		Mean Diff + SD	D.F.	t-value	p-value	Remark
1	Sapravahan mala pravriti	TG	AT1	1.10 ± 0.45	38	0.70	>0.05	#
		CG		1.00 ± 0.46				
		TG	AT2	2.25 ± 0.64	38	0.00	>0.05	#
		CG		1.90 ± 0.64				
2	Muhurmuhurmalaktam	TG	AT1	1.00 ± 0.37	29	0.00	>0.05	#
		CG		1.00 ± 0.38				
		TG	AT2	2.13 ± 0.62	29	0.65	>0.05	#
		CG		2.27 ± 0.59				
3	Udara shoola	TG	AT1	1.05 ± 0.52	36	0.57	>0.05	#
		CG		1.16 ± 0.60				
		TG	AT2	2.11 ± 0.66	36	0.24	>0.05	#
		CG		2.05 ± 0.71				
4	Presence of *E. Histolytica* in stool	TG	AT1	0.50 ± 0.51	38	3.94	<0.001	***
		CG		1.10 ± 0.45				
		TG	AT2	1.15 ± 0.37	38	5.10	<0.001	***
		CG		2.00 ± 0.65				
5	Presence of mucous in stool	TG	AT1	1.15 ± 0.49	38	0.66	>0.05	#
		CG		1.25 ± 0.44				
		TG	AT2	1.70 ± 0.66	38	1.84	>0.05	#
		CG		2.10 ± 0.72				

N.B.-TG = trial group, CG = Control Group, S.D = Standard Deviation, d. f.= Degree of freedom, N = t = test of significance, n = no. of patients each group, p = probability; *** = Highly significant at 0.1% level, ** = Highly significant at 0.2% level, * = significant at 1% level, # = insignificant with p-value > 0.05

On observation it has been found that, lower middle-class family member was affected more. It might be due to persons from the lower socio-economic group owing to their poor education and low standard living condition particularly in personal hygiene are definitely more prone to any infection. It has been observed that, most of the patients were doing Vishamasana. Vishamasana is responsible in derangement of Agni. As a result, Valasa is formed which is expelled in the shape of mucous with frequent defecation. Maximum patients had history of Mandagni. This might be due to excessive production of Kapha and Ama in Pravahika which suppress the natural stage of Agni present in body and that may lead to Mandagni develops in patients.

The trial drug was found to be statistically significant to reduce most of the symptoms like Sapravahana Malapravriti, Muhurmuhurmalaktam, Udara Soola and presence of mucous in stool. It might be due to Deepana, Pachana property of Sunthi, Pippali and Vatashamaka property of Tila, this formulation might be effective on Sapravahana Malapravriti. Grahi Guna of Bilwa and Deepana, Pachana property of Sunthi and Pippali may be helpful to relieve Muhurmuhur Malaktam. Pain may be reducing due to Shoola Prashamana and Vatanulomana property of Shunthi and Pippali. As most of the drugs found in this current formulation have Ushna Veerya and Bilwa antagonise Kapha, so this trial drug might be reduce mucous in stool. The control drug Metronidazole shown significant result to reduce most of the symptoms as compare to trial drug. Because the metronidazole is already a standard and established drug and it has an anti-protozoal action.

CONCLUSION

Pravahika is one of the commonest diseases of Annavaha and Pureeshavaha srotas in present era. Improper dietary habits and stressful lifestyle may lead to Agni Dushti and subsequently the disease Pravahika. Apart from these factors, socio-economic condition also plays an important role in causing and aggravating the disease. The therapeutic effect of this formulation was observed as Vata-kaphasamaka, Agni Deepaka, Vatanulomaka, digestive, anti-amoebic, anti-diarrhoeal, anti-spasmodic, anti-bacterial and anti-ulcerative property. On the basis of all results obtained in the study it can be concluded that, this combination is effective clinically and statistically in reducing most of the signs and symptoms of Pravahika. No any hazardous effects have been reported by the patients during the study or in follow up. This is very important in acceptance of Ayurveda worldwide. As the study sample was very small, further study of larger group of patients may help to understand detail mode and site of action of the drugs.

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